UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,

Plaintiffs,

v.

Case No. 2:22-cv-00223-Z

U.S. FOOD AND DRUG ADMINISTRATION, et al.,

Defendants,

and

DANCO LABORATORIES, LLC,

Intervenor-Defendant.

DANCO LABORATORIES, LLC'S RESPONSE IN SUPPORT OF THE FEDERAL DEFENDANTS' MOTION TO HOLD IN ABEYANCE THE MOTION TO INTERVENE FILED BY STATES OF MISSOURI, KANSAS, AND IDAHO

Danco Laboratories, LLC ("Danco") submits this response to the Federal Defendants' motion to hold in abeyance the motion to intervene filed by the States of Missouri, Kansas, and Idaho.¹

Danco concurs with the Federal Defendants' request that the Court hold in abeyance the States' motion to intervene pending resolution of Supreme Court proceedings with respect to this

¹ The States violated Local Rule 7.1(a) in filing their intervention motion without conferencing with Danco and by not stating Danco's position in their motion. Fifth Circuit caselaw is clear that "an intervenor 'must accept the proceedings as he finds them.' " *Sierra Club v. Espy*, 18 F.3d 1202, 1206 n.3 (5th Cir. 1994) (quoting *In re Geisser*, 554 F.2d 698, 705 n.6 (5th Cir. 1977)). In this proceeding, Danco is an Intervenor-Defendant and plainly would be "affected by the requested relief." Local Rule 7.1(a); *see also* States' Suggestions in Support of Mot. to Intervene at 2 n.1, ECF. No. 152 ("For the purpose of Intervenors' Motion to Intervene and Suggestions in Support, *both Defendants and Defendant-Intervenor* will be referred to collectively as 'Defendants.'") (emphasis added). Danco expressly states that it opposes the States' motion.

Court's April 7, 2023 Memorandum Opinion and Order. The Federal Defendants and Danco have moved expeditiously to seek review in the Supreme Court. They each filed petitions for certiorari on September 8, 2023, just over three weeks after the Fifth Circuit's ruling partially affirming and partially vacating this Court's April 7th Order. When Plaintiffs filed a conditional cross-petition on October 12, 2023, the Federal Defendants and Danco responded to that conditional cross-petition eight days ahead of the deadline to do so. All three petitions will be fully briefed in the Supreme Court before Thanksgiving and submitted for the Supreme Court's conference on December 8, 2023.

In these circumstances, abeyance until resolution of the Supreme Court proceedings makes sense as a matter of judicial efficiency. It will avoid this Court taking up potentially unnecessary complex legal questions, avoid unnecessary expenditure of party and court resources, and avoid a second round of briefing after the Supreme Court has ruled. If the original Plaintiffs lack standing to assert claims about FDA's actions in 2016 and 2021—a question teed up for the Supreme Court's review—the States' intervention motion cannot be granted because federal jurisdiction never attached. *See, e.g., Harris v. Amoco Prod. Co.*, 768 F.2d 669, 675 (5th Cir. 1985) (describing as "well-settled" that there must be "'[a]n existing suit within the court's jurisdiction" as "a prerequisite of an intervention") (citation omitted); *Lopez v. Sw. Airlines Co.*, No. 3:08-cv-01975-O, 2013 WL 12121233, at *5-6 (N.D. Tex. July 10, 2013) ("In the absence of original plaintiffs with standing, the legal effect of the intervention is itself called into question."). And the Court's resolution of other issues presented by the States' intervention request—such as venue, exhaustion, statute of limitations, and administrative law—will also potentially be affected by the Supreme Court's proceedings on the petitions for certiorari.

In the alternative, Danco concurs with the Federal Defendants' request for an extension of time to respond to the intervention motion—*i.e.*, until 30 days after the Court's resolution of the Federal Defendants' motion. The States' intervention motion was filed in this Court on November 3, 2023. Four days later, Danco filed its opposition to Plaintiffs' conditional crosspetition in the Supreme Court, and Danco is currently drafting its reply in support of its petition for certiorari, which will be filed Tuesday, November 21. Danco's counsel have longstanding plans with extended family over Thanksgiving weekend (and again over the Christmas and New Year's holidays). The States' motion is based on new material and new legal theories related to their purported standing, which Danco will need to thoroughly research and analyze in responding to the intervention motion.

Unlike when Danco moved to intervene, the States' intervention motion is anything but straightforward. No party disputed that Danco, as the manufacturer of the product that Plaintiffs challenge as unlawfully approved by FDA, satisfied the standard for intervention. The States' motion, by contrast, is contested and will require thorough briefing. Danco also moved to intervene within 60 days of Plaintiffs filing suit; the States wish to join the fray a year after this high-profile case began. In that intervening period, the procedural ground of this litigation has profoundly shifted: the Supreme Court has stayed this Court's April 7th Order while it considers whether to grant petitions for certiorari, and this Court has stayed Defendants' deadlines to answer or respond to the Complaint pending resolution of those appellate proceedings. Deferring the States' intervention motion until the Supreme Court has ruled on the petitions for certiorari and the preliminary-injunction phase of this case is completed will avoid effort and expense by the Court and parties that may be mooted.

CONCLUSION

For the reasons stated above, and those in the Government's Motion, Danco concurs in the

Government's Motion to Hold in Abeyance the States' Motion to Intervene.

November 15, 2023

Respectfully submitted,

/s/ Jessica L. Ellsworth

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CERTIFICATE OF SERVICE

I certify that on November 15, 2023, I electronically filed the foregoing Response using the CM/ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties of record.

/s/ Jessica L. Ellsworth